7-24-78

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EEE BRANCH REVIEW

DATE: IN 6/23/78 OUT 7/24/78 IN _____ OUT _____ IN _____ OUT _____

FISH & WILDLIFE ENVIRONMENTAL CHEMISTRY EFFICACY

FILE OR REG. NO. 8G 2068

PETITION OR EXP. PERMIT NO. 7969 EUP-10

DATE DIV. RECEIVED _____

DATE OF SUBMISSION _____

DATE SUBMISSION ACCEPTED _____

TYPE PRODUCTS(S): I, D, H, F, N, R, S _____

DATA ACCESSION NO(S). _____

PRODUCT MGR. NO. Zink

PRODUCT NAME(S) RONILIN, BAS 352F

COMPANY NAME BASF Wyandotte Corp.

SUBMISSION PURPOSE Data Review

CHEMICAL & FORMULATION _____

100.3 Purpose of Submission

Data Review only

103.0 Acute toxicity

103.1,2 Bird

Bobwhite quail - greater than 2510 mg/kg. ✓

103.1,4 Aquatic Invertebrate

Daphnia magna - 4.0 mg/l ✓

103.2 Subacute toxicity

103.2,.2 Bird

Mallard Duck - greater than 5620 ppm ✓

105.0 Conclusions

All of the studies submitted for review were found to be adequate to support registration under Section 3 regulations and proposed guidelines.

R. W. Felthousen WC for JWA

July 24, 1978
Richard W. Felthousen, Senior Specialist
Environmental Safety Section
Ecological Effects Branch

DATA REVIEW NUMBER: ES VII C.I

TEST: Acute Oral LD_{50}

SPECIES: Bobwhite Quail (Colinus virginianus)

RESULTS: The acute oral LD_{50} of BAS 352 F (Ronlin) to the bobwhite quail was estimated to be greater than 2510 mg/hg

CHEMICAL: Vinclozolin Technical 96.5%

TITLE: "Acute Oral LD_{50} - Bobwhite Quail BAS 352 F Final Report"

ACCESSION NO: None provided — 92194-002 //

STUDY DATE: May 16, 1978

RESEARCHER: Wildlife Inter. LTD. ✓

REGISTRANT: BASE Wyandotte Corporation ✓

VALIDATION CATEGORY: Core Data

R. W Felthousen - Reviewer 7. 1978
see coversheet
sm (12-21-92)

sm

Additional Information (Comment Sheet)

A. Additional Test Data

1. Intent of study - to determine the acute oral toxicity of RONILIN to an upland game bird species.

2. Methodology/Protocol

a. Test material: Vinvlozolin Tech. 96.5%

b. Test animals:

Species: Bobwhite quail
Age : 20 weeks
Sex : male/female
Number: 110 birds/pen - 5 of each sex.

c.

c. Test Conditions:

Housing: Beacon Battery Brooders
Temperature: 68 F
Photo period: 14:10 LD regimen
Basal Diet: Game bird Starter Ration

d. Treatment:

Test dosage: Each bird was individually weighed an and dosed on the basis of milligrams of material per kilograms of body weight. The ratio of experimental material to diluant was adjusted so that each bird received an approximately constant volume to body weight dose.

tant

Dosage Levels:

398,631, 1000, 1590 and 2510 mg/kg

e. Husbandry:

Ration and water were available ad libitum throughout the study. Feed was withheld from test birds for 15 hours prior to administration of toxicant.

f. Statistical Analysis

Probit Analysis

3. Additional Test Results

There were no mortalities at any dosage level tested and no overt symptoms of toxicity. At the 2510 and 1590 mg/kg dose levels there was a dose related reduction in body weight for the first 3-day period and a reduction in feed consumption during the first seven d days.

B. Validation Category

This study has been classified as "core" data in that it is scientifically sound and satisfies the intent of the proposed guidelines.

C. Category Repairability

N/A

D. Additional Data Required

None

E. Comments

Although the report says the study was statistically analyzed using the probit analysis technique it is obvious from the results that no analysis, other than "eyeballing" was necessary. Therefore, reporting that the LC_{50} was greater than 2510 mg/kg is acceptable.

In addition, there is an error (transposition of numbers) for bird #10 (1000 mg/kg) in the amount of Exp. Material Rcvd. The value listed is 0.2129, should be 0.2192. It also appears that the 2 in the fourth decimal place is some mathematical artifact that cannot be explained with the given data.

%AI = 96.5 %

DATA REVIEW NUMBER: ES VII 4.1

TEST: 48-HOUR LC_{50}

SPECIES: Water Flea (Daphnia magna)

RESULTS: The 48 hour LC_{50} is 4.0 mg/l, while the no effect level is 1.0 mg/l.

CHEMICAL: BAS 352 F

TITLE: "The Acute Toxicity of BAS 352 F - BWC Project VIII-1-H-145 to the Water Flea"

ACCESSION NO: None provided

STUDY DATE: April 28, 1978

RESEARCHER: Union Carbide Environmental Services UCE

REGISTRANT: BASF Wyandotte Corporation

VALIDATION CATEGORY: (Core) Data

CATEGORY REPAIRABILITY: N/A

Additional Information/Comment Sheet

A. Additional Test Data

1. Intent of Study - to determine the 48-hour LC_{50} of RONILIN (BAS 352 F) to an aquatic invertebrate.

2. Methodology/Protocol (Test practices followed those recommended by the Committee on Methods for Toxicity tests with Aquatic Organisms (1975).

a. Test material: BAS 352 F
b. Test organisms
Species - Daphnia magna
Age - 1st instar (20 hrs. old)
c. Test conditions -

Water - water was obtained from a small lake in Westchester County, N.Y. The water was filtered and intensively aerated prior to use.
pH - 7.10
Total Hardness - 64 mg/l as $CaCO_3$
Total alkalinity - 32 mg/l as $CaCO_3$
Temperature - 17.8 CC $\pm$0.3 CC

d. Treatment

Methods

The test was conducted in 250 ml glass beakers containing 200 ml of water. The test was started by introducing the toxicant into a 1 liter volumetric flask containing dilution water, thoroughly mixing the toxicant and dilution water and then decanting 200 ml into each of four 250 ml beakers.

Concentrations

A control, solvent control, 1.0, 1.8, 3.2, 5.6 and 10.0 mg/l.

Replicates

Four replicates of each concentration were run

Biological Loading

Five organisms were placed in each 250 ml beaker.

e. Husbandry

Twenty hours prior to starting a bioassay, approximately 14 adults with full brood chambers were isolated into soft lake water. The following morning the newly released instarswwwwe carefully removed with an eye dropper and distributed to ten test beakers.

f. Statistical Analysis

Speakman - Kaerber Estimator

3. Additional Test Results

The no effect level was observed to be 1.0 mg/l.

4. References

American Public Heath Asso. 1976. Standard Methods for the Examination of Water and Wasterwater. 14th Ed. N.Y. 1193 pp.

Committee on Methods for Toxicity Tests with Aquatic Organisms. 1975. Methods for Acute Toxicity Tests with Fish Macro-invertebrates and Amphibians EPA-660/3-75-009. p. 61.

Finney, D. J. 1971. Statistical Method in Biological Assay Assay, 2nd Ed. Griff. Landon. p. 668

B. Validation Category

This study has been classified as "core" data in that it is scientifically sound and satisfies the intent of the proposed guidelines.

C. Category Repairability

N/A

D. Additional Data Required / Discussion

None

E. Comments

1. The no effect level was observed to be 1.0 mg/l, however the parameter (s) observed were not mentioned.

2. A Finney Probit analysis of the data calculates the 48-hour LC_{50} to be 3.646 mg/l. This represent a difference of .354 mg/l from the Spearman Ka"rber estimate of 4.0. In so much as the difference is ~~less than 10 percent~~ (8.85%) and because the lower confidence interval does not go below 1 g mg/l the ~~dufferebce us bit eibsudered ti be sugbufucabt.~~ difference is not considered to be significant.

DATA REVIEW NUMBER: ES VII. E. 1

TEST: Eight-Day Dietary, LC_{50}

SPECIES: Mallard Duck (Anas platyrhynchos)

RESULTResults: The LC_{50} of BAS 352 F in the Mallard Duck is estimated to be greater than 5620 ppm.

CHEMICAL: BAS 352 F, Vinylozolin Technical 96.5%

TITLE: "Eight-Day-Dietary LC_{50} - Mallard Duck BAS 352 F Final Report.

ACCESSION NO: Not provided

STUDY DATE: May 15, 1978

RESEARCHER: Wildlife International LTD.

REGISTRANT: BASF Wyandotte Corporation

VALIDATION CATEGORY: "Core"

CATEGORY REPAIRABILITY? N/A

ABSTRACT:

The 8-day dietary LC_{50} of RONILIN to mallard ducks was estimated to be greater than 5620 ppm. No symptoms of abnormal behavior were seen at any dosage level.

Additional Information / Comment Sheet

A. Additional Test Data

1. Intent of study - to determine 8-day dietary LC_{50} of RONILAN to mallards.

2. Methodology/Protocol

a. Test material: Vinclozolin Tech. 96.5%
b. Test animals:
age - 14 day old birds
sex- no regard to sex of bird
number - 10 birds/per

C. Test Conditions:

Temperature - 72 F
Photoperiod - 14:10 LD regimen
Diet: Wildlife Int. Ltd's game bird starter ration

D. Treatment:

The birds were exposed to the appropriate dietary concentrations for five days, and then maintained on toxicant-free diet for an additional 3-day observation

Concentrations:

Diets were prepared to include 562, 1000, 1780, 3160 and 5620 ppm of toxicant.

E. Husbandry:

Starter ration and water were available ad libitum throughout the study.

F. Statistical Analysis

Probit Analysis

3. Additional Test Results

Mortality - The test material caused no mortalities at any dosage level.

3. Food Consumption - Only at 5620 ppm did food consumption appear to be depressed.

   Body Weight - no apparent effects seen.

   Symptoms of Toxicity - no overt symptoms of toxicity or behavioral abnormalities.

   Ration Analysis:

Protein	20%
Fat	6.5%
Fiber	4.0%
Calcium	1.2%
Phosphorus	0.7%

B. Validation Category

This study has been classified as "core" data andiis adequate to support registration.

C. Category Repairability

N/A

D. Additional Data Required// Discussion

None

E. Comments

Although the report says the study was statistically analyzed using the probit analysis technique it is obvious from the results that no analysis other than "eyeballing" was necessary. Therefore, reporting that the LC_{50} was greater than 5620 ppm is acceptable.

BASF Wyandotte Corporation
100 Cherry Hill Road
P.O. Box 181
Parsippany, NJ 07054

Attention: Dr. Donald M. Yoder

Gentlemen:

Subject: Bonilan® Fungicide (Straw)
EPA Experimental Use Permit No. 7969-EUP-18
Effective Dates: 3/2/79 to 3/2/80
Quantity Authorized: 3,000 lbs. Active Ingredients

On the basis of the information furnished by the applicant and the annexed program, an Experimental Use Permit under Section 5 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (86 stat. 983), is hereby issued for the named pesticide. Shipment and/or use under this permit is subject to the provisions of 40 CFR 172.

The issuance of an experimental use permit does not exempt the permittee from compliance with any applicable State pesticide regulations. Prior to shipment you should consult the State Pesticide Regulatory Officials of any State in which you intend to conduct your experimental program.

A temporary tolerance for residues of the active ingredient in or on the raw agricultural commodity strawberries have been established under provisions of the Federal Food, and Drug, and Cosmetic Act.

Based upon the experimental programs submitted, this product may be shipped for use under this permit to Arkansas, California, Florida, Illinois, Indiana, Kentucky, Louisiana, Maryland, Minnesota, Missouri, New Jersey, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Tennessee, Texas, Virginia, Washington, and Wisconsin.

The labeling submitted in connection with the application for an experimental use permit is acceptable subject to the following comments, and a stamped copy is enclosed for your records. This labeling, with required changes, must be used for all shipments under this experimental use permit. Submit five copies of revised labeling for our records.

1. The statement "Not for sale to any person other than a participant or cooperator of the EPA - approved Experimental Use Program" must appear on the label.

2. The label may bear no reference to an EPA Registration Number.

3. We note in your "Warranty Paragraph" that you disclaim the control over use. The provisions of the Federal Insecticide, Fungicide, and Rodenticide Act, under which experimental use permits are issued, require you to have control over the use; therefore, this statement must be modified or deleted.

4. The statement "For use only at an application site of a cooperator and in accordance with the terms and conditions of the experimental use permit" must appear on the label.

5. The statement "All applicable directions, restrictions, and precautions on the EPA registered label are to be followed," should appear after the specific directions for use.

6. The statement "This labeling must be in the possession of the user at the time of pesticide application," must appear on the label.

It is the responsibility of the permittee to ensure that residues in all treated crops do not exceed established tolerances prior to allowing treated crops into commercial channels of trade. If established tolerances are exceeded the crops must be destroyed or used for research purposes only.

All information required under the regulations for registration will be required prior to registration or petitioning for permanent tolerances. Refer to the Federal Register of July 3, 1975, page 28242.

7. The statement "Do not rotate with other crops for 12 months following the last application." must appear under use precautions on the label.

To evaluate your applications for registration under FIFRA, Section 3, the following information will be needed:

I. <u>Environmental Chemistry</u>:

1. The directions for use require multiple treatments. You must give maximum number of applications and maximal rate, pounds active ingredient per acre, per Season.

2. Either add a label restriction, "Do not rotate with other crops for 12 months following the last application," or submit rotational crop data to show fate of soil residues in the following crop planted in the same site.

We have ~~re-evaluated~~ 'reconsidered' this test & it is invalid

3. Attached Table 1, Summary of environmental chemistry data requirements by intended use pattern indicates data requirements for registration of the subject pesticide under Section 3 of FIFRA, as amended.

II. Environmental Safety:

1. The 96-hour LC_{50} for bluegill sunfish is unacceptable as the test substance is inadequately described. Submit percentage of active ingredient in the test material when applying for Section 3 Registration.

2. The 96-hour LC_{50} for Rainbow trout is unacceptable as insufficient mortality results were obtained to statistically calculate a valid LC_{50}. The experiments reported that due to insolubility, the product was not tested at levels over 18 ppm and therefore, complete mortality data was unavailable. It is suggested that you consult the following publications for alternative solvents:

   a. Methods for Acute Toxicity Test with Fish, Macroinvertebrates and Amphibians, EPA-600/3-75-0009, April 1975. Project Officer-Charles E. Stephan.

   b. Standard Methods for the Examination of Water and Wastewater. 1975 American Public Health Association.

III. Efficacy:

1. Effects of pesticide product on the quality of flavor and other quality factors such as size, color, and ripening should be evaluated as part of this experimental use program.

The Regulations for the Enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, providing for the issuance of experimental use permits, require that periodic reports be submitted at three-month intervals.

Sincerely,

Henry Jacoby
Product Manager (21)
Fungicide-Herbicide Branch
Registration Division (TS-767)

Enclosure

TSHJACOBY:LNR226.2:RAVEN:x479-2800:DCR#38891:2/28/78